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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/083,590 06/25/93 ARTAVANIS-TSAKONAS S 7326015

EXAMINER

SCHEINER, T

18M1/0905

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NEW YORK, NY 10036-2711

ART UNIT

PAPER NUMBER

DATE MAILED 1806

22

09/05/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 5/29/96
- ☒ This action is **FINAL**.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 68-74, 91 & 92 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 68-74, 91 & 92 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

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Part III DETAILED ACTION

Claim 90 has been canceled; claims 68-74, 91 and 92 are pending in the application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68-74, 91 and 92 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "a molecule having the antigenicity of a Notch protein" is vague and indefinite because no particular portion of Notch is identified; the new recitation is still broad enough to encompass epidermal growth factor since both Notch and EGF contain the same cysteine-rich EGF repeats, and thus both have Notch "antigenicity." The specification is not enabling for correlating the presence of malignancies, nervous system disorders, or benign disproliferative disorders with aberrant expression of proteins with Notch "antigenicity."

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 68-74, 91 and 92 are rejected under 35 U.S.C. § 103 as being unpatentable over Ellisen et al. (Cell, vol. 66, pp. 649-661, August 23, 1991).

Ellisen et al. disclose the human Notch homolog TAN-1 and suggest that alterations in the structure and expression of TAN-1 contribute to transformation or progression in some T-cell neoplasms, and to neural differentiation. Ellisen et al. do not screen for malignancy, diseases or disorders of the nervous system, or benign disproliferative disorder using TAN-1 levels, but it would have been obvious for one of ordinary skill in the art to have done so because Ellisen et al. suggest that there is a correlation between aberrant TAN-1 expression and malignancy,

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diseases or disorders of the nervous system, and benign disproliferative disorder.

Applicants urge that Ellisen *et al.* do not disclose a screening assay and the reference concerns the truncation of *TAN-1* RNA in T lymphoblastic leukemic cells due to a translocation resulting in breakpoints within an intron of *TAN-1*. Applicants urge that Ellisen cannot render the instant invention obvious because the effect of a translocation within a gene on the expression of the gene product is unpredictable (i.e., expression could be increased or decreased), thus one of ordinary skill in the art would not expect that gene expression levels could be used to screen for malignancy or disorders of the nervous system. These arguments have been considered, but are not persuasive. Ellisen *et al.* show that aberrant expression is associated with malignancy or nervous system disorders; the instant claims are drawn to detection of aberrant Notch levels, and actually recite that either an increase or a decrease is associated with malignancy or nervous system disorders. One of ordinary skill in the art would have recognized that it is aberrant expression, not increased or decreased expression *per se* that is associated with malignancy or nervous system disorders and Ellisen *et al.* show that aberrant expression is associated with malignancy or nervous system disorders.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8/2/96



TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800